



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/312-2021

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER: MEDICLUS CO., LTD.

No. 1210, 134, Gongdan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, KOREA

DEVICE/S:

- ✓ Dental root canal sealer
- ✓ Dental temporary filling material
- ✓ Dental composite resin
- ✓ Dental temporary cement

BRAND NAME/S: full list of brand names in annex 1

MODEL/S: full list of models in annex 1

FIRST ISSUE: 23/02/2021 **CURRENT ISSUE:** 07/05/2021 **REVISION Nr.:** 01 **EXPIRING DATE:** 27/05/2024

This certificate is also composed by n. 1 annex made of 1 page.



Dipl.- Ing. Feridoon Sergizzarea

MTIC INTERCERT Certification Body

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CERTIFICATE ■ CERTIFICATO ■ ZERTIFIKAT ■ ZERTIFİKA ■ CERTIFICADO ■ گواهینامه ■ ΠΙΣΤΟΠΟΙΗΤΙΚΟ ■ شهادة ■ 証明書 ■ 인증서



C E R T I F I C A T E

ANNEX No. 1 TO THE FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/312-2021

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

<u>DEVICE/S:</u>	<u>BRAND NAME/S:</u>	<u>MODEL/S:</u>
✓ Dental root canal sealer	✓ Any-Seal RC ✓ One-Fil	✓ AS10GBX1S ✓ OS2GBX1S
✓ Dental temporary filling material	✓ Once-Fil Flow ✓ Ezi-Crown	✓ OF1GBS5S-B ✓ OF1GBS5S-Y ✓ Ezi-Crown LC (A1, A2, A3)
✓ Dental composite resin	✓ Any-Core ✓ Any-Com Flow	✓ Any-Core tooth(A3) ✓ Any-Core white ✓ Any-Core blue ✓ Any-Com Flow Kit ✓ Any-Com Flow Rainbow ✓ Any-Com Flow Refill (Any-Com Flow A1, Any-Com Flow A2, Any-Com Flow A3, Any-Com Flow A3.5, Any-Com Flow A4, Any-Com Flow B1, Any-Com Flow B2, Any-Com Flow B3, Any-Com Flow C2, Any-Com Flow C3, Any-Com Flow D2, Any-Com Flow OA2, Any-Com Flow OA3, Any-Com Flow TL, Any-Com Flow OWT, Any-Com Flow YTL, Any-Com Flow RTL)
✓ Dental temporary cement	✓ Any-Temp	✓ Any-Temp NE

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[Signature]
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